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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,281	11/30/2001	Wen-Jen Hwu	9516-026-999	2126

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EXAMINER
OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,281	HWU, WEN-JEN	
	Examin r	Art Unit	
	Clinton Ostrup	1614	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-45 are pending in this application.

Priority

Priority to Provisional U.S. Application Number 60/250,130, filed December 1, 2000 has been acknowledged.

Restriction of Inventions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, drawn to methods of treating cancer, classified in class 436, subclass 64.

II. Claims 22-33, drawn to methods of reducing or preventing an adverse effect associated with the administration of temozolomide, classified in class 514, subclass 974.

III. Claims 34-37, drawn to a method of increasing the therapeutic efficacy of temozolomide, classified in class 514, subclass 946.

IV. Claims 38-40, drawn to a pharmaceutical composition and kit comprising said composition, classified in class 514, subclass 323.

V. Claims 41-42, drawn to a method of increasing the dosage of temozolomide that can be safely and effectively administered to a patient, classified in class 514, subclass 970.

VI. Claims 43-45, drawn to a method or reducing or preventing the adverse effects associated with the administration of thalidomide, classified in class 514, subclass 810.

The inventions are distinct, each from the other because of the following reasons:

Inventions IV and I, II, III, V, and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used to treat cancer, nausea, or headaches.

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I requires the treatment of cancer while invention II has a separate utility as a method of reducing or preventing an adverse effect associated with the administration of temozolomide to a patient with nausea or headaches. See MPEP § 806.05(d).

Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I requires the treatment of cancer while invention III has a separate utility as a method of increasing the efficacy of temozolomide for the treatment of nausea and headaches. See MPEP § 806.05(d).

Inventions I and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I requires the treatment of cancer while invention V has a separate utility as a method of increasing the dosage of

temozolomide that can be safely and effectively administered to a patient with nausea or headaches. See MPEP § 806.05(d).

Inventions I and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I requires the treatment of cancer while invention VI has a separate utility as a method of increasing the dosage of thalidomide that can be safely and effectively administered to a with nausea or dry skin. See MPEP § 806.05(d).

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II requires methods of reducing or preventing an adverse effect associated with the administration of temozolomide while invention III has a separate utility as a method of increasing the efficacy of temozolomide to a patient with nausea or headaches. See MPEP § 806.05(d).

Inventions II and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II requires methods of reducing or preventing an adverse effect associated with the administration of temozolomide while invention V has a separate utility as a method of increasing the dosage of temozolomide that can be safely and effectively administered to a patient with nausea or headaches. See MPEP § 806.05(d).

Inventions II and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention II requires methods of reducing or preventing an adverse effect associated with the administration of temozolomide while invention VI has a separate utility as a method of reducing or preventing the adverse effects associated with the administration of thalidomide to a patient with nausea or dry skin. See MPEP § 806.05(d).

Inventions III and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III requires a method of increasing the therapeutic efficacy of temozolomide while invention V has a separate utility as a as a method of increasing the dosage of temozolomide that can be safely and effectively administered to a patient with nausea or headaches. See MPEP § 806.05(d).

Inventions III and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III requires a method of increasing the therapeutic efficacy of temozolomide while invention VI has a separate utility as a method of increasing the dosage of thalidomide that can be safely and effectively administered to a with nausea or dry skin. See MPEP § 806.05(d).

Inventions V and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are

shown to be separately usable. In the instant case, invention V requires a method of increasing the dosage of temozolomide that can be administered safely and effectively, while invention VI has a separate utility as a method of increasing the dosage of thalidomide that can be safely and effectively administered to a with nausea or dry skin. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, III, IV, V, or VI restriction for examination purposes as indicated is proper.

Election of Species

Upon election of Group I or II in response to the restriction requirement set forth above, that elected group will be further subject to an election of species requirement, for search purposes only.

This application contains claims directed to the following patentably distinct species of the claimed invention:

I. Cancer treatment methods for: primary cancer and metastatic cancer.

II. Additionally, should primary cancer be elected, the following patentably distinct species of conditions related to primary cancer include: dermatological melanoma, ocular melanoma, and mucosal melanoma.

III. However, should metastatic cancer be elected, the following patentably distinct species of conditions related to metastatic cancer include: skin, subcutaneous tissue, lymph nodes, lung, liver, spleen, adrenal gland, intestine, bone, brain, heart, and kidney.

Thus, should Group I or Group II be elected, applicant must elect one method of treating primary **OR** metastatic cancer to be treated and within each respective category, elect one condition related to said primary or said metastatic cancer.

Further, should Group II be elected, applicant must elect **one** specific adverse effect to be treated from those listed in claims 29-30.

Upon election of Group V in response to the restriction requirement set forth above, applicant must elect **one** specific adverse effect to be treated from those listed in claim 42.

If Group VI is elected in response to the restriction requirement set forth above, applicant must elect **one** specific adverse effect to be treated from those listed in claims 44-45.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1&2, 22, 34, 38, 41, and 43 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

January 31, 2003

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1600